

**UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA)	CRIM. NO. 4:17-CR-0403
)	
v.)	(Chief Judge Brann)
)	
RAYMOND KRAYNAK)	

**BRIEF OF THE UNITED STATES IN OPPOSITION TO
DEFENDANT’S SUPPLEMENTAL MOTION
TO WITHDRAW GUILTY PLEA**

The United States hereby submits its brief in opposition to the defendant Raymond Kraynak’s supplemental motion to withdraw his guilty plea, Doc. 253; 254, and in support thereof submits the following grounds:

I. RELEVANT BACKGROUND

On May 9, 2022 the United States filed its brief in opposition to the defendant’s motion to withdraw his guilty plea. Doc. 251. On July 7, 2022, Kraynak filed a supplemental motion and supporting brief to withdraw guilty plea based on the Supreme Court’s recent decision in *Ruan v. United States*, 142 S.Ct. 2370 (2022). Doc. 253; 254. In replying

to the recently filed supplemental motion and brief, the United States will not repeat its earlier arguments but, rather, incorporates them by reference. The Court has set Kraynak's motion for a hearing on August 3, 2022.

II. ARGUMENT

Because by pleading guilty Kraynak admitted that he knowingly distributed controlled substances contrary to law, *Ruan v. United States* does not support Kraynak's claim of innocence.

Kraynak's current submission, aimed at getting out from under his guilty plea, seizes upon the recent decision of the Supreme Court in *Ruan v. United States*, __U.S.__, 142 S. Ct. 2370 (2022) for support. His attempt to leverage *Ruan* in his favor, while certainly resourceful, fails in view of the distinguishing circumstances in this case. Unlike the defendants in *Ruan*, Kraynak entered a guilty plea to the indictment, after hearing all the evidence in the government's case, and, in pleading guilty, admitted that he knew his conduct in prescribing drugs was not for legitimate medical purposes, outside the usual professional practice, and therefore not authorized under 21 U.S.C § 841. Moreover, the trial

evidence in the case, both direct and circumstantial, amply demonstrated Kraynak's knowledge and intent that his conduct deviated from that professional standard.

1. The Supreme Court's holding in Ruan

In contrast to Kraynak's mid-trial guilty plea at the close of the government's case, in *Ruan*, and the companion case, *Kahn v. United States*, the Supreme Court reversed the convictions of two doctors, who were found guilty after jury trials of violating 21 U.S.C. §841 by distributing controlled substances not issued for a legitimate medical purpose and outside the usual course of professional practice. 142 S.Ct. at 2375. The defendants in those cases argued that their prescriptions were "authorized" under § 841(a)(1) because they fell within the usual course of professional practice, and that, even if they did not comply, the government was required to prove that they knowingly and intentionally deviated from the standard. *Id.* at 2375-76.

As the Supreme Court stated, § 841(a)(1) makes it a federal crime, "[e]xcept as authorized[,] . . . for any person knowingly or intentionally . .

. to manufacture, distribute, or dispense . . . a controlled substance,” such as opioids. 21 U.S.C. § 841(a). *Id.* at 2377. Under applicable regulations, a prescription is “authorized” when a licensed physician issues it “for a legitimate medical purpose . . . acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). *Id.* at 2377-78. The defendants in *Ruan* and *Khan* contested the trial courts’ jury instructions and argued that the juries were not properly instructed on the *mens rea*, or mental state required for conviction, specifically that the defendants knew they were acting in an unauthorized manner. *Id.* at 2376-77.

The Supreme Court held that, in order for a licensed physician otherwise authorized by law to be convicted for prescribing controlled substances not for a legitimate medical purpose and outside the usual course of professional practice, the government must prove that the doctor acted knowingly or intentionally, that is, that the defendant knew he or she was acting in an unauthorized manner or intended to do so. *Id.* at 2376. The Supreme Court vacated both convictions and remanded to

the Eleventh and Tenth Circuits, to see if the jury instructions complied with the *mens rea* standard the Court established and whether any instructional error was harmless. *Id.* at 2382.

In *Ruan*, the Supreme Court rejected the government’s “substitute *mens rea* standard”—“objectively reasonable good-faith effort,” as drawn from *United States v. Moore*, 423 U.S. 122 (1975)—because that “standard would turn a defendant’s criminal liability on the mental state of a hypothetical ‘reasonable’ doctor, not on the mental state of the defendant himself or herself.” *Id.* at 2381-82. But, significantly, the Court stated, “[t]he Government . . . can prove knowledge of a lack of authorization through circumstantial evidence,” and “the scope of a doctor’s prescribing authority” remains tethered to “objective criteria such as ‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice.’” *Id.* at 2382.

2. *Unlike the defendants in **Ruan**, Kraynak admitted that he knowingly and intentionally distributed controlled substances in an unauthorized manner.*

While Kraynak, like the defendants in *Ruan* and *Kahn*, was a physician convicted of violating § 841(a)(1), the similarities stop there. First of all, the doctors in *Ruan* and *Kahn* were convicted at the conclusion of jury trials where the district courts' instructions to the juries on the § 841 scienter requirement was held to be erroneous by the Supreme Court. Kraynak, however, pled guilty, so there was never any instruction, erroneous or otherwise, given to the jury. But more important, in pleading guilty, Kraynak admitted that on multiple separate occasions charged in the indictment he knowingly and intentionally distributed opioids that were not for a legitimate medical purpose and outside the usual course of professional practice. The Court's thorough and probing colloquy made abundantly clear that Kraynak's knew his prescribing activity was not authorized when he committed the violations of § 841(a)(1).

During the guilty plea colloquy, the Court advised Kraynak of the elements of the § 841(a)(1) violations to which he was admitting his guilt:

* * *

Q. [by the Court] To demonstrate you are guilty of these offenses, the government would be required to prove, one, that you distributed and dispensed or caused to be distributed or dispensed a mixture or substance containing a controlled substance, two, that you distributed and dispensed or caused to be distributed and dispensed a controlled substance outside the usual course of professional practice and not for a legitimate medical purpose, three, that you did so knowingly intentionally and, four, the controlled substance was the specific substance identified in counts one through 12 of the indictment. Do you understand that, sir?

A. [by Kraynak] Yes.

Change of plea, 8-9.

As explained by the Court, the third element is the *mens rea* that the government would have to prove before he could be convicted, i.e., that Kraynak acted knowingly or intentionally when he distributed and dispensed controlled substances, not for a legitimate medical purpose, and outside the usual course of his professional practice. Change of Plea, 8. The Court thus confirmed Kraynak's understanding that by pleading

guilty he was admitting all three elements of the offenses, including his personal knowledge that his conduct in prescribing the drugs was not in the usual course of professional practice, not for a legitimate medical purpose, and therefore not authorized under § 841(1)(a).

In addition to advising him of the *mens rea* requirement, the Court confirmed that Kraynak admitted that the testimony and evidence presented during three weeks of trial established his knowledge that the prescriptions charged in the indictment were outside the usual course of professional practice and not for a legitimate medical purpose. During the guilty plea colloquy, the Court had the following exchange with Kraynak:

Q. Dr. Kraynak, do you fully admit to the testimony and evidence presented at trial that demonstrates that you prescribed the controlled substances identified in counts one through 12 of the indictment to the identified patients during the timeframes alleged *and that you did so knowing that the prescriptions were outside the usual course of professional practice and not for a legitimate medical purpose?*

A. Yes.

Change of Plea, 20, lines 7-14 (emphasis added).

Kraynak's admission that he knowingly and intentionally distributed opioids without authorization also echoed the stipulation and acknowledgement in the plea agreement of his culpability for the deaths of his patients:

In addition to the counts of conviction, pursuant to U.S.S.G. § 1B1.2 and 1B1.3 (relevant conduct), the defendant and the United States stipulate that the defendant committed the additional offenses of ***knowingly and intentionally distributing*** Alprazolam, Hydrocodone, Carisoprodol, Oxycodone, Temazepam, Diazepam, and Zolpidem, Schedule II **controlled substances, outside the usual course of professional practice and not for legitimate medical purposes**, and that the deaths of R.C, D.H., A.K, M.L., and C.S as charged in Counts 13 through 1-7 of the Indictment resulted from the use of the substances.

Doc. 216, p. 9. (emphasis added).

Finally, before accepting his guilty plea and adjudging him guilty, the Court confirmed that Kraynak was pleading guilty after he reviewed all the elements of the offenses and admitted all the trial testimony and evidence forming the factual basis for the guilty plea:

Q. Very well. With all the information I reviewed with you thus far, is it still your desire to plead guilty?

A. Yes.

Q. Are you pleading guilty because you are, in fact, guilty?

A. Yes, yes.

Q. Are you willing to waive your right to a trial by a jury of your peers?

A. Yes.

Q. Dr. Kraynak, do you now plead guilty?

A. I do.

Change of Plea, 20.

Kraynak's guilty plea thus leaves no doubt that, with a full understanding of the mental state required to be proven under *Ruan*, he admitted prescribing controlled substances with knowledge that his conduct was not authorized – that he knew the prescriptions he dispensed were not for a legitimate medical purpose and were outside the usual course of professional practice. During the guilty plea colloquy, the Court presciently described the

elements that the government would need to prove beyond a reasonable doubt precisely as found by the Supreme Court in *Ruan*, just nine months later. And Kraynak unhesitatingly admitted that the evidence presented at trial met all the elements of §841, including the *scienter* requirement determined by the Supreme Court in *Ruan*. Given that the Court in its guilty colloquy carefully reviewed the elements, including the knowledge and intent that the distribution of controlled substances was outside the usual professional practice later, it is clear that the jury likewise would have been correctly instructed on the *mens rea* requirement had Kraynak elected to proceed with the trial.

Kraynak's guilty plea reveals no basis to believe his guilty plea was either involuntary or unsupported by his admission of the conduct adduced at trial. His allegation of insufficient evidence presented at trial based on *Ruan* is an argument that he forfeited in giving up his trial rights and in admitting that the trial evidence established his guilt, both factually and legally. Accordingly, the

Supreme Court’s decision in *Ruan* provides Kraynak with no additional support for his dubious claim of innocence.

3. *The trial evidence showed that Kraynak knew his conduct was not authorized.*

In *Ruan*, the Supreme Court held that the United States “can prove knowledge of a lack of authorization through circumstantial evidence,” and “the scope of a doctor’s prescribing authority” remains tethered to “objective criteria such as ‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice.’” *Ruan* at 2382. As the trial evidence demonstrated, Kraynak clearly knew that his prescriptions for controlled substances were not authorized and that they were not for legitimate medical purposes and outside usual professional practice. Moreover, the evidence established that he knowingly exceeded the scope of his prescribing authority measured by applicable objective criteria for legitimate medical purposes and usual professional practice. *Id.*

As Dr. Stephen Thomas testified based on his review of the defendant’s patient files, Kraynak prescribed high doses of opioids, in progressively higher quantities and often in dangerous combination with

benzodiazepines, and other medications, that increased risks of respiratory failure, overdose, and death. Kraynak's own patient files showed that he prescribed high-dose opioid regimens to victim patients at significantly higher risk of abuse and overdose, including patients with documented histories of "Oxy selling", drug abuse, drug overdose, psychiatric hospitalization, attempted suicide, rollover car accidents where the patient fell asleep while driving, liver and kidney disease, chronic breathing difficulties, sleep studies showing decreased oxygen saturation while sleeping, acute respiratory failure, medical staff reports of patients' gross intoxication, syncope, and loss of consciousness, visible evidence of hand and arm abscesses indicating intravenous drug use, and alcohol and substance dependence and treatment. Blood levels at the time of death for patients prescribed opioids and other drugs by Kraynak well exceeded the therapeutic ranges. And, in several cases, Kraynak's patient files documented periods of abstinence which increased drug sensitivity and the risk of overdose when he re-issued high-dose opioid prescriptions for those patients. Kraynak's files reflect

that even after he issued “boot letters” to terminate and discharge patients from his practice, he nevertheless continued to prescribe them high doses of opioids and benzodiazepines.

In addition to his patient files, trial testimony and evidence established that Kraynak and his staff received calls and correspondence from pharmacists, pharmacy staff, and insurance companies raising questions about the high-dose opioid prescriptions that he issued. Pharmacists even refused to fill Kraynak’s prescriptions on multiple occasions because of medical risks of overdose and death presented. Several patients testified that they were sexually propositioned by Kraynak during office visits when he would renew opioid prescriptions. Other patients testified that their family members called Kraynak and his staff to report overdose and abuse of opioids prescribed by Kraynak. Some family members requested that Kraynak stop writing patient prescriptions.

Testimony and evidence at trial, both direct and circumstantial, established beyond a reasonable doubt that Kraynak knew his opioid

prescribing activity was outside the usual professional practice and not for legitimate medical purposes. As Dr. Thomas testified, Kraynak's prescribing behavior and patient record keeping were at odds with the standards applicable to physicians prescribing opioids and benzodiazepines, whether medical or osteopathic doctors. Despite the circumstances putting him directly on notice that his patients were at high risk of overdose, serious bodily injury, and death as a result of the high-dose, multi-drug prescriptions he issued, he nevertheless continued to prescribe opioids in increasing amounts. Thus, even apart from Kraynak's admission at his guilty plea that the evidence was sufficient to convict him, the evidence presented at trial, including the testimony of patient witnesses, pharmacists, Dr. Thomas, and others overwhelmingly established that Kraynak knowingly and intentionally violated §841 by issuing prescriptions he knew were outside the usual professional practice and not for legitimated medical reasons. His claim of innocence thus fails, and his motion to withdraw guilty plea should be denied.

III. CONCLUSION

For all the reasons stated herein, the United States respectfully requests that the Court deny the defendant's motion to withdraw his guilty plea.

Respectfully submitted,
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 19th day of July 2022, a copy of the attached

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was sent via ECF to:

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